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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,439	01/05/2007	Bruno Lussier	09555.0151USWO	4659

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EXAMINER	
BRADLEY, CHRISTINA	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
02/04/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,439	LUSSIER ET AL.	
	Examiner	Art Unit	
	CHRISTINA BRADLEY	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-24,50-56 and 74-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *3-24,50-56 and 74-80* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/5/07, 5/4/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of the species (hexenoyl trans-3)hGRF(1-44)NH2 and the species chronic obstructive pulmonary disease in the reply filed on 11/24/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 3-24, 50-56 and 74-80 are pending.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 3-6, 8-14, 22-24 and 74-79 are rejected under 35 U.S.C. 102(b) as being anticipated by Gravel et al. (US 6,458,764).

Gravel et al. teach a pharmaceutical composition comprising:

An hydrophobic GRF analog of formula A:

X—GRF-peptide (A)

wherein;

the GRP peptide is a peptide of formula B;

A1-A2-Asp-Ala-Ile-Phe-Thr-A8-Ser-Tyr-Arg-Lys-A13-Leu-A15-Gln-Leu-A18-Ala-Arg-Lys-Leu-Leu-A24-A25-Ile-A27-A28-Arg-A30-R_0 (B)

wherein,

A1 is Tyr or His;
A2 is Val or Ala;
A8 is Asn or Ser;
A13 is Val or Ile;
A15 is Ala or Gly;
A18 is Ser or Tyr;
A24 is Gln or His;
A25 is Asp or Glu;
A27 is Met, Ile or Nle;
A28 is Ser or Asn;
A30 is a bond or any amino acid sequence of 1 up to 15 residues;
R_0 is NH_2 or NH-(CH_2)n-$CONH_2$, with n=1 to 12 and;

X is a hydrophobic tail anchored via an amide bond to the N-terminus of the peptide and said hydrophobic tail defining a backbone of 5 to 7 atoms;

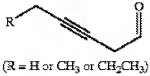
wherein said backbone can be substituted by C_{1-6} alkyl, C_{3-6} cycloalkyl, or C_{6-12} aryl;

and comprises at least one rigidifying moiety connected to at least two atoms of the backbone;

said moiety selected from the group consisting of double bond, triple bond, saturated or unsaturated C_{3-9} cycloalkyl, and C_{6-12} aryl

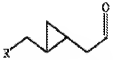
and wherein X is selected from the group consisting of:

1



(R = H or CH_3 or CH_2CH_3)


($R = H$ or CH_3 or CH_2CH_3)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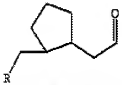
($R = H$ or CH_3 or CH_2CH_3)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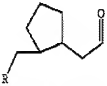
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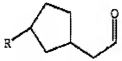
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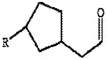
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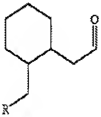
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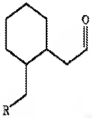
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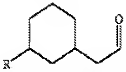
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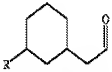
($R = H$ or CH_3 or CH_2CH_3)

and a pharmaceutically acceptable carrier (claim 2 of Gravel et al.) The composition satisfies all of the structural limitations of instant claims 74-79. With respect to claim 74, the GRF analogs of Gravel et al. are growth hormone secretagogues (see Example IV which illustrates the GH-releasing potency of the claimed GRF analogs). With respect to claim 75, the compounds of Gravel et al. are GRF analogs. With respect to claim 76, formula A taught by Gravel et al. is a subgenus of the formula in the claim. With respect to claim 77, formula A taught by Gravel et al. is identical to formula in the claim. With respect to claim 78, Gravel et al. teach GRF analogs wherein A30 is a bond (i.e. the hGRF(1-29)NH_2 analogs) and wherein A30 is an amino acid sequence corresponding to positions 30-44 of a natural GRF peptide (i.e. hGRF(1-44)NH_2 analogs) (Examples I-IV). With respect to claim 79, Gravel et al. teach GRF analogs wherein the GRF peptide is SEQ ID NO: 3 (i.e. hGRF(1-44)NH_2 analogs) and SEQ ID NO: 5 (i.e. the hGRF(1-29)NH_2 analogs) (Examples I-IV).

Gravel et al. do not explicitly teach that the compositions are intended for increasing muscle function in a subject. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Because the compositions taught by Gravel et al. are structurally identical to the instantly claimed invention, they must be capable of performing the intended recited in the instant claims.

Gravel et al. teach a method of administering the GRF analogs above to subjects (claims 3-10). Gravel et al. teach the administration of GRF analogs by subcutaneous injection (Example 1, Experiment 3), satisfying the method step of claim 22. Gravel et al. teach the

administration of GRF analogs at a dose of 30 μg/kg or 20 μg/kg for 40-45 kg subjects, which equals 0.8-1.35 mg (Example 1, Experiment 3), satisfying the method step of claims 23 and 24. Gravel et al. do not explicitly teach that the purpose of the method is to increase muscle function as recited in instant claims 3-6, 8-14 and 22-24. Because the compounds taught in Gravel et al. and the manner of administering them are identical to the instant invention, the effect on muscle function is inherently met.

5. Claims 3-14, 22-24 and 74-80 are rejected under 35 U.S.C. 102(b) as being anticipated by Larocque et al. ("Anchoring rigid hydrophobic chains to stabilize growth hormone-releasing factor," APS Poster, 2001).

Larocque et al. teach a composition comprising (trans3 hexenoyl) hGRF(1-44)NH_2, a GRF analog that is identical to instant SEQ ID NO: 7 (Figure 1, Figures 3A and B). Larocque et al. do not explicitly teach that the compositions are intended for increasing muscle function in a subject. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Because the compositions taught by Gravel et al. are structurally identical to the instantly claimed invention, they must be capable of performing the intended recited in the instant claims.

Larocque et al. teach a method of administering the GRF analogs above to subjects (claims 3-10). Gravel et al. teach the administration of GRF analogs by subcutaneous injection (Figures 3A and B), satisfying the method step of claim 22. Larocque et al. teach the

administration of GRF analogs at a doses ranging from 3 μg/kg or 81 μg/kg for 45 kg subjects, which equals 0.135-3.645 mg (Figures 3A and B), satisfying the method step of claims 23 and 24. Larocque et al. do not explicitly teach that the purpose of the method is to increase muscle function as recited in instant claims 3-14 and 22-24. Because the compound taught in Larocque et al. and the manner of administering it is identical to the instant invention, the effect on muscle function is inherently met.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 50-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gravel et al. (US 6,458,764). The teachings of Gravel et al. are presented above. Gravel et al. do not teach a package comprising the GRF analogs and pharmaceutically acceptable carriers described above in combination with instructions for increasing muscle function. Because Gravel et al. teach that the GRF analogs described above can be used for a variety of pharmaceutical purposes including treating GH deficiency, treating pituitary dwarfism, wound or bone healing, treating

osteoporosis, improving anabolism, inducing a lipolytic effect, and upgrading the somatroph function (claims 3-10), one of ordinary skill in the art would have been motivated to package said GRF analogs with instructions on how to administer them. MPEP § 2112.01.III. states: "Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. *In re Ngai*, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004)" Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

8. Claims 50-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larocque et al. ("Anchoring rigid hydrophobic chains to stabilize growth hormone-releasing factor," APS Poster, 2001). The teachings of Larocque et al. are presented above. Larocque et al. do not teach a package comprising (trans3 hexenoyl) hGRF(1-44)NH_2 and a pharmaceutically acceptable carrier described above in combination with instructions for increasing muscle function. Because Larocque et al. teach that TH9507 can be used treat age-related diseases and conditions, one of ordinary skill in the art would have been motivated to package (trans3 hexenoyl) hGRF(1-44)NH_2 with instructions on how to administer it. MPEP § 2112.01.III. states: "Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. *In re Ngai*, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004)" Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

9. Claims 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (US 6,423,693) in view of Gravel et al. (US 6,458,764). Schwartz et al. teach that growth hormone releasing hormone (GHRH) has therapeutic utility in stimulating the production and secretion of growth hormone (GH) (col 2, lines 30-37) and specifically in the treatment of cachexia in chronic diseases such as cancer (col 2, lines 38-48, col 34, line 44 - col 35, line 18) and the treatment of chronic obstructive pulmonary disorder (col 11, lines 55-65). Schwartz et al. teaches that current limitations of recombinant GHRH therapy include the short half-life of the peptides in vivo and the requirement for frequent administration (1-3 times/day) of either subcutaneous or intravenous injections (col 2, lines 49-57). Schwartz et al. propose as an alternative to administration of GHRH peptides, a gene-therapy approach to circumvent these limitations.

Schwartz et al. do teach a method of administering GRF analogs of formula A.

Gravel et al. teach GRF analogs of formula A (presented in detail above). Gravel et al. teach that the analogs have improved biological potency and prolonged activity, increased anabolic potency and prolonged activity, i.e. capable to substantially elevate insulin-like growth factor I (IGF-I) levels when chronically administered in humans and animals (col 4, lines 34-48).

It would have been obvious to one of ordinary skill in the art to use the GFR analogs of formula A taught by Gravel et al. in the method of treating wasting and COPD taught by Schwartz et al. The skilled artisan would have been motivated to do so given that Gravel et al. teach that the GRF analogs have improved potency and prolonged activity which overcomes the disadvantages with GRF therapy identified by Schwartz et al. There would have been a

reasonable expectation of success given that Gravel et al. administer the GRF analogs of formula A to animals and that they exhibit an ability to induce GH secretion (Examples 3 and 4). With respect to claim 17-21, Schwartz et al. do not teach the specific criteria for diagnosing patients with wasting (i.e. BMI, fat-free mass index and ideal weight). It would have been obvious to select patients with severe wasting in view of Schwartz et al. and to optimize the diagnostic criteria of patients through routine experimentation. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

10. Claims 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (US 6,423,693) in view of Larocque et al. ("Anchoring rigid hydrophobic chains to stabilize growth hormone-releasing factor," APS Poster, 2001). Schwartz et al. teach that growth hormone releasing hormone (GHRH) has therapeutic utility in stimulating the production and secretion of growth hormone (GH) (col 2, lines 30-37) and specifically in the treatment of cachexia in chronic diseases such as cancer (col 2, lines 38-48, col 34, line 44 - col 35, line 18) and the treatment of chronic obstructive pulmonary disorder (col 11, lines 55-65). Schwartz et al. teaches that current limitations of recombinant GHRH therapy include the short half-life of the peptides in vivo and the requirement for frequent administration (1-3 times/day) of either subcutaneous or intravenous injections (col 2, lines 49-57). Schwartz et al. propose as an alternative to administration of GHRH peptides, a gene-therapy approach to circumvent these limitations.

Schwartz et al. do teach a method of administering GRF analogs of formula A.

Larocque et al. teach a composition comprising (trans3 hexenoyl) hGRF(1-44)NH_2,

a GRF analog that is identical to instant SEQ ID NO: 7 (Figure 1, Figures 3A and B, presented in detail above). Larocque et al. teach that this analog has a prolonged half life in human serum which translates into a higher GH-releasing potency in pigs, inducing GH release on a 8-hour period in a pulsatile fashion following sc administration at low doses (0.11 to 3 mg/kg). Larocque et al. teach that this analog is therefore a powerful and long-acting GH secretagogue with all the physiological advantages of hGRF and is in clinical development for the stimulation of anabolism in several age-related diseases and conditions, such as recovery following hip fracture, COPD and frail elderly.

It would have been obvious to one of ordinary skill in the art to use the (trans3 hexenoyl) hGRF(1-44)NH_2 taught by Larocque et al. in the method of treating wasting and COPD taught by Schwartz et al. The skilled artisan would have been motivated to do so given that Larocque et al. teach that the (trans3 hexenoyl) hGRF(1-44)NH_2 has improved potency and prolonged activity which overcomes the disadvantages with GRF therapy identified by Schwartz et al. There would have been a reasonable expectation of success given that Larocque et al. administer the GRF analogs of formula A to animals and that they exhibit an ability to induce GH secretion. With respect to claim 17-21, Schwartz et al. do not teach the specific criteria for diagnosing patients with wasting (i.e. BMI, fat-free mass index and ideal weight). It would have been obvious to select patients with severe wasting in view of Schwartz et al. and to optimize the diagnostic criteria of patients through routine experimentation. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

11. The following documents are publications of applications that are the subject of double patenting rejections presented below: US 7,316,977, US 20090011985, US20090253623 and US 20090088383. These documents disclose matter that is substantially similar to Gravel et al. presented above.

12. Claims 50-56 are rejected under 35 U.S.C. 103(a) as being obvious over US 7,316,977 **OR** US 20090011985 **OR** US20090253623 **OR** US 20090088383 in a manner analogous to the rejection of these claims over Gravel et al. presented above.

13. Claims 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 7,316,977 **OR** US 20090011985 **OR** US20090253623 **OR** US 20090088383 in view of Schwartz et al. in a manner analogous to the rejection of these claims over Gravel et al. in view of Schwartz et al. presented above.

Because these rejections are substantially identical to the rejections already made they are not written out for the sake of brevity.

The applied references have a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in

the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 3-14, 22-24, 50-56 and 74-80 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 7,316,997. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1-8 of U.S. Patent No. 7,316,997 recite a method of administering a pharmaceutical composition comprising (hexenoyl trans 3)hGRF(1-44)NH_2. Claims 7 and 8

state that the dose is about 2 mg. Claims 5 and 6 state that administration is by intravenous, oral, transdermal, subcutaneous, mucosal, intramuscular, intranasal, intrapulmonary, parenteral, intrarectal and topical. The claims do not explicitly teach that the intended use of the method or composition is to increase muscle function as recited in instant claims 3-14, 22-24 and 74-80. Because the composition and the manner of administering it is identical to the instant invention, the effect on muscle function is inherently met. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Because the compositions taught by the '997 patent are structurally identical to the instantly claimed invention, they must be capable of performing the intended recited in the instant claims.

With respect to claims 50-56, it would have been obvious to package the composition claimed in U.S. Patent No. 7,316,997 with instructions for use in the claimed method. MPEP § 2112.01.III. states: "Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. *In re Ngai*, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004)" Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

16. Claims 15-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 7,316,997, as applied to claims 3-14, 22-24, 50-56 and 74-80 above, in further view of Schwartz et al. Although the

conflicting claims are not identical, they are not patentably distinct from each other. The claims of '997 do not teach a method of administering GRF analogs to patients with wasting.

Schwartz et al. teach that growth hormone releasing hormone (GHRH) has therapeutic utility in stimulating the production and secretion of growth hormone (GH) (col 2, lines 30-37) and specifically in the treatment of cachexia in chronic diseases such as cancer (col 2, lines 38-48, col 34, line 44 - col 35, line 18) and the treatment of chronic obstructive pulmonary disorder (col 11, lines 55-65). Schwartz et al. teaches that current limitations of recombinant GHRH therapy include the short half-life of the peptides in vivo and the requirement for frequent administration (1-3 times/day) of either subcutaneous or intravenous injections (col 2, lines 49-57). Schwartz et al. propose as an alternative to administration of GHRH peptides, a gene-therapy approach to circumvent these limitations.

It would have been obvious to one of ordinary skill in the art to use the GFR analog claimed in the '997 patent in the method of treating wasting and COPD taught by Schwartz et al. The skilled artisan would have been motivated to do so given that the '997 patent indicates that the GRF analog is suitable for therapeutic use, suggesting that it has overcome the disadvantages with GRF therapy identified by Schwartz et al. With respect to claim 17-21, Schwartz et al. do not teach the specific criteria for diagnosing patients with wasting (i.e. BMI, fat-free mass index and ideal weight). It would have been obvious to select patients with severe wasting in view of Schwartz et al. and to optimize the diagnostic criteria of patients through routine experimentation. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

17. Claims 3-14, 22-24, 50-56 and 74-80 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-88 of copending Application No. 12/239,697 **OR** claims 1-88 of copending Application No. 12/239,708 **OR** claims 1-88 of copending Application No. 12/239,712. An independent rejection is made over each of these copending applications but because the rejections are substantially identical they are presented in consolidated form for the sake of brevity. Although the conflicting claims are not identical, they are not patentably distinct from each other.

The claims of the '395 application recite a method of administering a pharmaceutical composition comprising GRF analogs that are identical to instant formula A including (hexenoyl trans 3)hGRF(1-44)NH_2. The claims of the copending applications '697, '708 and '712 recite a method of administering a pharmaceutical composition comprising GRF analogs that are identical to instant formula A including (hexenoyl trans 3)hGRF(1-44)NH_2 (claim 59), pharmaceutical compositions comprising the GRF analogs (claims 1-52, 71-74 and 79-88) and packages comprising the GRF analogs and instructions for use (claims 53-70 and 75-78). Claims 14 and 15 state that the dose is about 0.0001-2 mg or 1-2 mg. Claims 16 and 17 state that administration is by intravenous, oral, transdermal, subcutaneous, mucosal, intramuscular, intranasal, intrapulmonary, parenteral, intrarectal and topical. The claims do not explicitly teach that the intended use of the method or composition is to increase muscle function as recited in instant claims 3-14, 22-24, 50-56 and 74-80. Because the composition and the manner of administering it is identical to the instant invention, the effect on muscle function is inherently met. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the

claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Because the compositions taught by the copending applications are structurally identical to the instantly claimed invention, they must be capable of performing the intended recited in the instant claims. With respect to claims 50-56, MPEP § 2112.01.III. states: "Where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. *In re Ngai*, 367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004)." This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

18. Claims 15-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20-34 and 89-104 of copending Application No. 11/877,395 **OR** claims 1-88 of copending Application No. 12/239,697 **OR** claims 1-88 of copending Application No. 12/239,708 **OR** claims 1-88 of copending Application No. 12/239,712, as applied to claims 3-14, 22-24, 50-56 and 74-80 above, in further view of Schwartz et al. (US 6,423,693). An independent rejection is made over each of these copending applications but because the rejections are substantially identical they are presented in consolidated form for the sake of brevity. Although the conflicting claims are not identical, they are not patentably distinct from each other. The claims of '997 do not teach a method of administering GRF analogs to patients with wasting.

Schwartz et al. teach that growth hormone releasing hormone (GHRH) has therapeutic utility in stimulating the production and secretion of growth hormone (GH) (col 2, lines 30-37)

and specifically in the treatment of cachexia in chronic diseases such as cancer (col 2, lines 38-48, col 34, line 44 - col 35, line 18) and the treatment of chronic obstructive pulmonary disorder (col 11, lines 55-65). Schwartz et al. teaches that current limitations of recombinant GHRH therapy include the short half-life of the peptides in vivo and the requirement for frequent administration (1-3 times/day) of either subcutaneous or intravenous injections (col 2, lines 49-57). Schwartz et al. propose as an alternative to administration of GHRH peptides, a gene-therapy approach to circumvent these limitations.

It would have been obvious to one of ordinary skill in the art to use the GFR analog claimed in the copending applications cited here in the method of treating wasting and COPD taught by Schwartz et al. The skilled artisan would have been motivated to do so given that the copending applications indicate that the GRF analog is suitable for therapeutic use, suggesting that it has overcome the disadvantages with GRF therapy identified by Schwartz et al. With respect to claim 17-21, Schwartz et al. do not teach the specific criteria for diagnosing patients with wasting (i.e. BMI, fat-free mass index and ideal weight). It would have been obvious to select patients with severe wasting in view of Schwartz et al. and to optimize the diagnostic criteria of patients through routine experimentation. Thus, the invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

19. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINA BRADLEY whose telephone number is (571)272-9044. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 8:30 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Christina Marchetti Bradley/
Examiner, Art Unit 1654

cmb